DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

October 10, 1980

Dr. Joshua Lederberg
President
The Rockefeller University
1230 York Avenue
New York, NY 10021

Dear Dr. Lederberg:

Thank you for your letter of September 26, 1980 and for sending me a copy of your American Journal of Medicine editorial on the need to allocate resources to the study of the predictive value of toxic effects of chemicals and other environmental hazards.

Your editorial mentioned that much or most of the laboratory information on toxicity which could be useful in predictive methodology is tucked away in company files. The FDA is, of course, another repository for such data and occasionally in a spare moment we talk of the desirability of compiling the animal findings and attempting to determine which were predictive for human toxicity and under what circumstances. No one has the time to do this, however, nor are funds available for this purpose because of higher priority contracts. Occasionally a drug company will attempt to show that a metabolite of one of its compounds is responsible for the toxic effects in an animal model and that this metabolite is not produced by humans. That is largely the extent of attempts at more sophisticated evaluation of data.

Perhaps you would agree that the most organized attempts at predicting toxic effects are those directed to in vitro and short term in vivo methods for detecting potential mutagenicity and carcinogenicity. I suspect that it will be a long time, however, before we would be willing to abandon long term carcinogenicity testing in animals, imperfect as it is. There is always an uneasy feeling about the exception to the rule.

You asked for some data on elective induction of labor. I have sent your letter to our Division of Metabolism and Endocrine Drug Products for reply. The subject was discussed before our Fertility and Maternal Health Advisory Committee and we can send you a transcript of the discussion plus any background data available. Much of the data on risk of nonmedically indicated elective induction is soft. The Committee, therefore, concluded not that the practice has been shown to be hazardous but that the benefit/risk ratio of elective induction for nonmedical indications had not been adequately established; consequently, the

labeling for oxytocics with respect to elective induction of labor should limit the use of the drug to medically indicated situations.

I enjoyed meeting you at the Hoechst Symposium and hearing your philosophical/technical presentation.

Sincerely yours,

M. J. Finkel

Marion J. Finkel, M.D.
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